Procedures for Review Task Management (Interim)

General Provisions

Article 1 The Procedures is developed with the view to ensure the quality & efficiency and continuous improvement of the review, according to Center for Drug Evaluation’s (hereinafter referred to as CDE) Principles and Procedures for Drug Review (Yao Shen Ye [2011] No. 56).

Article 2 The Procedures applies to the management of review tasks for chemical drugs at its pilot phase. The review task management for Traditional Chinese Medicines and ethnic medicines and biological products can be implemented with reference to the Procedures.

Article 3 CDE implements a risk-based review task management model. In this model, in order to ensure the effective management of the review tasks, CDE established a review task management mechanism featuring centralized management, democratic supervision, openness and transparency.

The Classification, Marking and Publicity of Review Tasks

Article 4 CDE review tasks are divided into the following six sequences:

1. Investigational New Drug Application (IND)
2. New Drug Application (NDA)
3. Bridging clinical trial application
4. Abbreviated New Drug Application (ANDA)
5. Supplementary Application
6. Re-registration for import

Article 5 The Office of Management and Communication is in charge of standardizing processing and marking of accepted review tasks in accordance with the application
information, to determine the sequence of the review tasks.

**Article 6** The risks of reviews carried by various disciplines in applications are reflected in the coefficients of difficulty and marked separately. Review tasks of different sequences should establish corresponding review channels, allocate appropriate review resources, and adopt different decision-making mechanisms and review procedures, as well as other management methods. The difficulty coefficient score sheet of various disciplines in the sequence of review tasks is shown in Annex I.

**Article 7** Review tasks of each sequence, in principle, shall be performed in accordance with the application order of the sequence. CDE can conduct priority review on related varieties based on clinical needs and the Principles and Procedures for Drug Review, and the principles for priority review shall be developed separately and disclosed afterwards.

The Office of Management and Communication shall perform uniform management of review tasks in accordance with the above principles, and publicize the sequence of tasks on CDE internal review system and CDE websites. The adjustment of review tasks in accordance with required procedures must also be publicized on CDE internal review system and CDE websites.

**Dispatching and Adjustment of Review Tasks**

**Article 8** The review offices should reasonably classify review tasks in light of the indications and the reviewers shall be relatively fixed, in order to facilitate the mutual coordination of different offices; and should clarify each reviewer’s task sequence in line with the risk level of review task of different sequences, the professional levels and titles of reviewers etc.

**Article 9** The Office of Management and Communication shall, in view of the indications and review sequence borne by each reviewer, assign the review tasks directly to reviewers and designate the chief-reviewers and co-reviewers. For disciplines in original application with difficulty coefficient $\geq 3$, the participating reviewers shall not be less than 2.
Article 10  After the review tasks are assigned, the chief-reviewer reporter shall confirm the difficulty coefficient, marks of special approval procedures and priority review, and review procedures marked by the Office of Management and Communication, and promptly return mis-assigned cases to the Office of Management and Communication for re-assignment; The director of review office may adjust the review tasks assumed by his/her office according to the actual internal work situation, including the adjustment of reviewers within the office, the addition of participating offices (with consents from the offices intended to be included), etc.; if there is a need to adjust the Review Reporting Office, the director of the current Review Reporting Office shall fill in the “CDE Internal Review Tasks Adjustment Approval Form” and report to the Office of Management and Communication for implementation after approval procedures. The above-mentioned task adjustment information shall be publicly notified.

Review Task Management of Various Offices and Positions

Article 11  The CDE Review Information System shall provide a working interface to the following positions:

Reviewers: indications oriented work interface / task sequence oriented work interface / chief-reviewers and co-reviewers oriented work interface / various review meetings oriented work interface. Each interface shall mark the activated review tasks. Meanwhile, the participation information of reviewer teams shall also be provided.

Director of Review Offices: indications oriented work interface / task sequence oriented work interface / chief-reviewers and co-reviewers oriented work interface / internal staff oriented task management interface/ various review meetings oriented work interface / director authorization & signatory oriented work interface / supplementary information oriented management interface. Each interface shall mark the activated review tasks. Meanwhile, the participation information of reviewer teams shall also be provided.

The work interface for relevant staff of the Office of Management and Communication and other comprehensive management offices shall be configured according to their job responsibilities.
CDE Charging Directors: Their work interface shall be configured in accordance with their respective work duties.

Various offices and positions shall, based on the above information, perform effective management on the review tasks. The Review Information System shall be improved constantly according to work needs.

**Article 12** The document management position of the Office of Management and Communication shall finish the Filing tasks within three working days after receiving registration application document. After CDE received SFDA electronic tasks, the project manager shall assign the supplement application tasks within 5 working days, and other types of review tasks within 10 working days to relevant reviewers.

**Article 13** The Office of Management and Communication shall, on the basis of task completion of previous review sequences, determine the basic number of review tasks of each sequence on the next stage (usually monthly). To encourage the continuous improvement of review efficiency, according to the difficulty coefficients of different task sequences, a 10-20% pressure test coefficient is to be added on the basis of the basic tasks of different sequences to increase corresponding tasks. The basic tasks and pressure tasks together constitute the active tasks of the next phase.

**Article 14** The activated review tasks shall be marked by the Office of Management and Communication after being discussed at the extend Directors’ Work Meetings and filed; and the various review posts and CDE leaders shall be clearly informed and the public notified.

**Article 15** The chief-reviewer reporter is responsible for organizing the co-reviewers to carry out discipline and comprehensive review on the activated review tasks in accordance with the relevant procedures of CDE. The chief-reviewers and co-reviewers of each discipline shall take the initiative to help work with the chief-reviewer reporter, and the number of discipline review tasks completed by each reviewer shall not be less than that of the tasks borne by him/her in the current round of activated tasks.

**Article 16** The director of each review office shall take charge of the overall management of the review tasks, and be responsible for overseeing the implementation of the activated review tasks assumed by the office, manage the review tasks of the
supplementary document, and adjust the classification of indications for reviewers of the office when necessary.

**Article 17** At the end of each review period (usually monthly), the Review Information System shall count up and calculate the per capita number of tasks of each Review office in this period, to form the task saturation index, which, together with other relevant indicators, constitute the examination and evaluation index system, as well as the basis to further determine the basic number of review tasks.

All comprehensive management offices shall periodically summarize and evaluate the implementation of review tasks, suggest improvements and optimization strategies, and gradually realize the goal of carrying out review task management on target review time.

**Article 18** The CDE charging director shall perform comprehensive, overall management and supervision on the review tasks under his/her care.

**Examination and Evaluation**

**Article 19** CDE shall establish the following parameter system to perform examination and evaluation on the efficiency and quality of the review tasks management: the basic task numbers, the coefficient of pressure tests, the coefficient of difficulty, task saturation index, delay index, synergy index. The evaluation parameters are defined in Annex II.

**Article 20** The Research and Evaluation Office shall analyze and evaluate the management and achievement of review tasks of each sequence regularly in alignment with the above parameters system, and develop the evaluation report.

**Article 21** The Human Resources and Information Office shall provide rewards and punishments comments and suggestions to relevant offices and individuals according to the above-mentioned evaluation report.
**Supplementary Articles**

**Article 22** The Office of Management and Communication shall assign the review tasks for supplementary document formally accepted by CDE to appropriate directors of Review Offices within 3 working days. Each office is responsible for the management of the review tasks for supplementary document. The review tasks for supplementary document are not to be included in the scope of parameter examination and evaluation. Each office’s review task sequence of supplementary document shall be separately and publicly notified.

**Article 23** Relevant comprehensive management offices are responsible for the supervision, evaluation and examination of the management or delay of each office’s review tasks for supplementary document.

**Article 24** This Procedures shall enter into force as of the date of release.

**Annex 1:**

**Table of difficulty coefficient of different disciplines in different task sequences**

<table>
<thead>
<tr>
<th>Task Sequence</th>
<th>CMC</th>
<th>Clinical</th>
<th>Pharmacology and Toxicology</th>
</tr>
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<tbody>
<tr>
<td>Investigational New Drug Application (IND)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New drugs</td>
<td>2.5</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Special dosage forms</td>
<td>3.5</td>
<td>33</td>
<td>22</td>
</tr>
<tr>
<td>New Drug Application (NDA)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registration Category 1, 2</td>
<td>5</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Registration Category 3 and 4</td>
<td>3.5</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Special dosage forms</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Bridging Clinical Trial Application</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Registration Category 3 (First Application)</td>
<td>3.5</td>
<td>2</td>
<td>0.5</td>
</tr>
<tr>
<td>Registered Category 3 (Non-first)</td>
<td>2.5</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Application</td>
<td></td>
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<td>-------------</td>
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<td></td>
</tr>
<tr>
<td>Registration classification 3.4</td>
<td>0.5</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>Registration Category 4</td>
<td>3.5</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Abbreviated New Drug Application (ANDA)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First generics</td>
<td>3</td>
<td>2</td>
<td>0.5</td>
</tr>
<tr>
<td>Others (clinical applications)</td>
<td>2</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Other (production applications)</td>
<td>2.5</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Re-registration</td>
<td>1</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>Supplementary Application</td>
<td>1 (Except item 3,4).</td>
<td>2 (for item 3,4)</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Notes:

1. The difficulty coefficients in this table are semi-quantitatively defined in a 5-point system.

2. The varieties of Priority Review (such as anti-HIV drugs, anti-drug-resistant TB drugs) shall be scored according to the type of the actual tasks.

3. Inactivated professional review shall not be scored.

4. The special formulations refer to fat emulsion, microspheres, micro-emulsion injection, liposome, transdermal patches, implantable preparations etc.

5. The difficulty coefficient ratings only apply to the newly applied tasks.

Annex 2: The definition of task management parameters in this Standard

**Basic task numbers:** the average amount of completed tasks of different task sequences in previous multiple time periods.

**The coefficient of stress tests:** additional review task ratio on the basis of the basic task numbers for each sequence or department, which is usually set between 10 to 20 percent according to difficulty coefficient of different sequences and review resources etc.
**Difficulty coefficient:** a 5-point index system representing CDE’s general labeling of the technical difficulty of the review task (sequence).

**Task saturation index:** the per capita number of activated review tasks at various departments in the current round of review.

**Delay index:** the proportion of uncompleted review tasks number three months after task activation accounting for the new round of activated review tasks. CDE has now clearly defined that task delays of varieties whose review have been suspended according to explicit regulations, such as waiting for test reports, are not included.

**Synergy index:** the ratio of the completed principal professional review tasks against participating review tasks in a period of time in each review department.

**Disclaimer:**
This document is for reference only. For any dispute, the Chinese version shall prevail.